# APPARATUS AND METHOD FOR HARVESTING BONE

The present invention relates to the field of surgery. The invention has particular utility in connection with the removal and collection of bone (harvesting) from the surface of one or more donor sites, and the preparation and placement of the autogenous bone material at a location in the patient, e.g. for use in grafting bone to osseous deficiencies, such as periodontal and dentoalveolar defects, bone deficiencies around dental implants, and numerous orthopedic applications that require grafting, and will be described in connection with such utility, although other utilities are contemplated.

Many reconstructive procedures used in medicine and dentistry involve the manipulation and healing of bones. Such procedures may involve changes in the position, orientation, shape and size of skeletal structures. A problem that is commonly encountered during such procedures is a lack of bone graft material. Bone graft material may be used in several applications, such as to fill between sections of bone that have been repositioned, to change surface geometry, or to add bone to an area that is deficient, such as in conjunction with periodontal surgery or dental implants in the patients' jaws.

The need to harvest small bone grafts from intraoral sites has been common in periodontal surgery to restore bone defects around teeth. In the case of dental implant surgery, bone grafts may be needed to augment atrophic alveolar ridges of the maxilla and/or mandible and the sinus floor to increase the dimension of these bone sites to accommodate and totally cover the endosseous portion of implant fixtures. Bone grafts also are used in conjunction with guided tissue regeneration; a technique that uses a membrane to isolate hard tissue from soft tissue sites and potentiates hard tissue healing.

It is often difficult to harvest adequate amounts of autogenous bone from intraoral sites. Therefore, clinicians often rely on non-autogenous sources of graft material, such as bone from cadaver sources (allografts or allogenic grafts), animal sources (xenografts or xenogeneic grafts), or synthetic bone substitutes (alloplasts). However, healing of non-autogenous material grafts is not as extensive or predictable as healing of autogenous bone; plus there is the additional cost of such non-

autogenous graft materials, which can be significant.

Clinicians use several techniques to remove bone for grafting for intraoral procedures. In one such technique rotary instruments, such as side cutting burrs or trephines, are used to remove a piece or section of cortical bone from a local intraoral site in the maxilla or mandible. The cortical bone is often morsalized into a particulate form, either manually with a rongeur like instrument or in a bone mill. The particulate bone is then combined with blood to form an osseous coagulum, which is then positioned and packed into the osseous defect around the teeth or implant. See Robinson, R.E. "Osseous Coagulum for Bone Induction", J. Periodontology 40:503(1969). Suction devices with filters have been fabricated and manufactured to collect the bone dust from rotary instruments. See Hutchinson, RA "Utilization of an Osseous Coagulum Collection Filter", J. Periodontology 44:668(1973). See also Goldman, et al., "Periodontal Therapy", pp 994-1005, C.V. Mosby Co., (1980); and Haggarty, et al., "Autogenous Bone Grafts: A Revolution in the Treatment of Vertical Bone Defects", J. Periodontology 42:626(1971). While such techniques are widely used by clinicians, the techniques have limitations, since sites to harvest sections of intraoral bone are limited in number and extent because of limited intraoral access, proximity to tooth roots, nerve structures and sinus cavities, and thin plates of bone.

Other techniques for harvesting bone include using chisels or osteotomes to remove and manually collect shavings from the surface. These instruments must be very sharp and the process is often awkward and time consuming. Other manual instruments such as bone files and rasps also remove bone. However, the efficiency of cutting and the ability to use the removed bone is greatly limited. Another technique is to collect bone dust generated by twist drills or taps used to prepare the sites for implant placement. However, much of the bone material may be lost while the site is being irrigated to cool the cutting instrument. When larger amounts of bone are needed for major reconstructive procedures, other sites such as the hip (anterior or posterior ilium), tibia, ribs, or the calvarium often are used. However, using such other sites necessitates a second surgical site, which may require postoperative hospitalization, and thus is less amenable, e.g. in the case of an out-patient dental procedure.

Various surgical devices have been proposed and/or are in use to harvest bone marrow samples for biopsy or devices such as rongeurs or bone cutters or punches to remove sections or convex edges of bone. Surgical devices also are in use in arthroscopy and endoscopy for cutting or drilling bone or tissue and removing the tissue fragments. Ultrasonic devices to cut bone also are in use; however, such devices require the removal of the irrigant and debris liberated by the apparatus. Each of these methods and/or devices, however, suffers from one or more deficiencies as applied to the collection of bone for grafting.

Yet other patented devices have been proposed; each of these, however, suffers from one or more deficiencies:

U.S. Patent Nos. 5,403,317 and 5,269,785 to Bonutti show a method and apparatus for the percutaneous cutting and removal of tissue fragments from human. The Bonutti device removes the tissue fragments by suction where it can be collected and then placed elsewhere in the patient from where originally obtained. Bonutti employs a flexible drill, and suction to remove the debris to an externally placed collection reservoir, where it is compressed before being replaced into the patient.

U.S. Patent No. 2,526,662 to Hipps discloses a bone meal extractor apparatus for mechanically removing bone meal from a donor bone site through a small percutaneous site using a drill. The drill shavings, which comprise primarily sub-surface bone, are then evacuated into an open cut that the drill passes through, for collection.

U.S. Patent No. 4,798,213 to Doppelt teaches a device for obtaining a bone biopsy for diagnosis of various bone diseases. The Doppelt device is intended to remove a core of bone using a tubular drill, while maintaining the architecture of the tissue. The sample is obtained from the marrow space and not intended from re-implantation.

U.S. Patent No. 5,133,359 to Kedem shows a hard tissue biopsy instrument in which samples are taken using a rotatably driven hollow needle.

U.S. Patent No. 4,366,822 to Altshuler discloses a method and apparatus for bone marrow cell separation and analysis. The Altshuler apparatus collects bone marrow cells in a filtration chamber on a filter interposed between a needle directed

into the bone marrow site and an aspirator or vacuum source, i.e. using negative pressure to withdrawal marrow cells through a needle.

U.S. Patent No. 5,052,411 to Schoolman teaches, a vacuum barrier attachment for shielding the operator of a medical tool from harmful aerosols and blood, etc. created by drilling, sawing types of actions, etc. The Schoolman device requires vacuum and is not intended for harvesting tissue for re-implantation.

U.S. Patent No. 4,722,338 to Wright et al. discloses a device instrument for removing bone that uses a shearing action similar to a rongeur to cut bone, with means for collecting fragments of bone as they are removed. The Wright et al. device reportedly is used mainly for the removal of projections or edges of bone using a shearing mechanism without the intent of harvesting the bone for grafting.

U.S. Patent No. 4,994,024 to Falk teaches an arthroscopy hook-clippers device that allows the unobstructed removal of tissue or bone with removal of the fragments by suction. The Falk device is intended for arthroscopy applications and with the removal of projections of tissue or bone and not specifically for the harvest of tissue for grafting.

Yet other prior art devices are disclosed in U.S. Patent No. 4,466,429 to Loscher et al. and U.S. Patent No. 4,844,064 to Thimsen et al.

The foregoing discussion of the prior art derives from my earlier PCT Application No. WO 97/11646, which describes a hand-held surgical instrument for the cutting, removal, and storage of bone surface shavings for use as autogenous bone grafts. The instrument is comprised of a blade mounted in a handle for holding and supporting said blade. The blade has a cutting structure adjacent its distal end. In a preferred form, the handle cooperates to provide a storage space adjacent the distal end of the blade for receiving harvested bone from the cutting structure. The instrument is held at an acute angle to the bone, and with minimal downward pressure, is drawn across the bone surface to cut and collect a thin shaving of bone. The blade is preferably retractable to allow the clinician access to harvested material. A plunger preferably is incorporated into the handle to serve both as a locking mechanism to secure the blade and as a means to advance and consolidate the bone in the distal aspect of the instrument.

The present invention provides enhanced functionality and reduced cost over the surgical instrument described in my aforesaid PCT Application No. WO 97/11646.

The invention is directed to a hand-held surgical instrument for the cutting, removal, and storage of bone surface shavings for use as autogenous bone grafts. The instrument is comprised of a blade and storage compartment coupled to a handle. The blade may be made from a section of metal that is oriented relative to a longitudinal axis of the handle to allow the operator to more easily cut or scrape and accumulate bone. The blade preferably is slid into place over a collection chamber and secured to prevent accidental removal. The collection chamber includes storage space adjacent the cutting edge of the blade for receiving harvested bone from the blade. The collection chamber may be coupled to a handle portion at a joint. The joint allows the user to orient the blade relative to the handle in order to access hard to reach locations. A pry bar may be employed to assist in removal of the blade from the collection chamber. The pry bar may be stored within the handle portion.

In use, the blade and collection chamber is held at an acute angle to the bone and the user applies a minimal downward pressure as the tool is drawn across the bone surface. Thin shavings of bone are cut by the cutting edge and collected in the collection chamber. The clinician can view the amount of harvested material through an opening, preferably a slot, provided in the blade.

In a preferred embodiment, the blade is removable and replaceable, while the handle is reusable.

In another preferred embodiment of the invention, the handle has an area of reduced mechanical strength or a flexible joint displaced from the cutting edge, the area of reduced mechanical strength allowing the cutting edge to be angularly positioned relative to a longitudinal axis of the blade.

The above and other objects, features, and advantages of the present invention will be apparent in the following detailed description thereof when read in conjunction with the appended drawings wherein the same reference numerals denote the same or similar parts, and wherein:

Figure 1 is a perspective view of an exemplary bone-harvesting instrument

consistent with the present invention;

Figure 2 is an exploded view of the bone-harvesting instrument of Figure 1;

Figure 3 is a profile view of the bone-harvesting instrument of Figure 1;

Figure 4 is a perspective view of a portion of a second embodiment blade consistent with the present invention;

Figure 5 is a an exploded view of a portion of the bone-harvesting instrument of Figure 1;

Figure 6 is a view similar to Figure 1 of an alternative embodiment of bone-harvesting instrument consistent with the present invention;

Figure 7 is a view similar to Figure 6, and illustrating loading of a blade into the handle of the instrument of the Figure 6 embodiment;

Figure 8 is a view similar to Figure 6 of yet another alternative embodiment of bone-harvesting instrument consistent with the present invention;

Figures 9, 10, 10A and 11 are views, similar to Figure 7, and illustrating loading of a blade into the handle of the instrument of the Figure 8 embodiment;

Figures 12-14 are views similar to Figure 7, and illustrating unloading of a blade from the handle of the instrument of the Figure 8 embodiment; and

Figures 15-16 illustrate packaging and handling of a blade with a hemostat.

Figure 1 shows a bone-harvesting instrument 100. The instrument 100 may have a handle portion 102, a collection chamber 104 and a blade 106. The handle portion 102 may have a first end 102A and a second end 102B. The handle portion 102 may have a removable end cap 150 in close proximity to the first end 102A for storage of a blade removal tool 200 (see Figure 3). In one embodiment, the collection chamber 104 may be coupled to the handle portion 102 through a flexible joint 108. In a preferred embodiment of the invention, the flexible joint is an area of reduced mechanical strength. The area of reduced mechanical strength allows the cutting edge of the blade to be angularly and/or rotationally positioned or bent to a desired angle and/or position relative to a longitudinal axis of the blade 106. In another embodiment, the flexible joint may be a ball and socket joint.

The area of reduced mechanical strength may be an area where the thickness is less than the thickness of a surrounding area. Alternatively, the area of reduced

mechanical strength may be an area where the material has a lower yield strength than the surrounding area. The area of reduced mechanical strength allows the collection chamber 104 to flex or bend relative to the handle portion 102.

Figure 2 shows an exploded view of the instrument 100 with the blade 106 spaced from the collection chamber 104. The collection chamber 104 preferably is a five-sided enclosure with a bottom 132, sidewalls 134 and an end wall 136. The interior volume of the collection chamber 104 may be used to hold accumulated bone shavings. The collection chamber 104 preferably is formed of stainless steel. Alternatively, collection chamber 104 may be molded from a polymeric material, preferably a medical grade plastic. The depth of the collection chamber 104 at the end opposite the end wall 136 preferably is less than the depth near the end wall 136. This allows the instrument to be used to access hard-to-reach locations.

A top surface 140 of the sidewall 134 defines a generally planar surface for supporting at least the cutting end of the blade 106. Extending from the top surface 140 may be a pair of opposing upstanding retainer members 142 and a pair of opposing stabilizing members 144. The retainer members 142 help secure the blade 106 to the collection chamber 104 during use and the stabilizing members 144 prevent the blade 106 from rotating. Each retainer member 142 includes a first cam surface 142A, a second cam surface 142B, and a ledge portion 142C (see Figure 5). The ledge portion 142C helps maintain the blade 106 in contact with the top surface 140 and the cam surfaces 142A and 142B help resist linear movement of the blade 106. The ledge preferably is spaced from the top surface 140 approximately the thickness of the blade 106.

In an alternative embodiment, a single pair of cam surfaces located on one side of the collection chamber are used to resist the linear movement of the blade 106.

In an alternative embodiment, a single stabilizing member, for example a post upwardly extending from the end wall 136, cooperates with an opening in the blade 106 to prevent rotation of the blade 106.

The blade 106 may be laser cut, wire electrical discharge machined (EDM), stamped or machined from metal, preferably stainless steel, or other suitable materials with similar hardness. The blade 106 has a first end 110, a second end 112, a middle

section 124 and at least one outwardly extending lobe 116, preferably a pair of outwardly extending lobes. The first end 110 includes an aperture 116 adjacent at least a portion of a cutting edge 114. Thus, the cutting edge 114 is drawn along a surface, generated shavings pass through the aperture 116 and are accumulated in the collection chamber 104. An opening 118 extends along a longitudinal axis of the blade 106. The opening 118 allows the user to visually check the amount of accumulated material and also provides a spring force to allow lobe/s 116 on the blade 106 to move inward to allow the blade 106 to pass the upstanding retainer members 142 on the collection chamber 104.

The second end 112 includes a stop mechanism 120 that prevents the blade 106 from traveling past its intended "use" position (see Figure 3) and a protrusion 122 that can be used to help extract the blade 106 from the collection chamber 104.

To couple the blade 106 to the collection chamber 104, the user first aligns the lobe/s 116 in the space between the upstanding retainer members 142 and the stabilizing member/s 144. The user then applies a force (F) to the end surface of the blade 106 and directs the force along the longitudinal axis of the blade 106 towards the end wall 136. The longitudinal force causes the lobe/s 116 on the blade 106 to contact the cam surface/s 142A on the retainer member 142 of the collection chamber 104. The cam surface/s 142A applies a compressive force ($F_o$) to the lobe/s 116 urging the lobe/s towards the centerline of the blade 106. The user continues to apply a longitudinal force to the blade 106 until the stop mechanism 120 on the blade 106 contacts the end wall 136 of the collection chamber 104. The blade is now in the "use" position. In the "use" position, the lobe/s 116 preferably are partially returned to their original "relaxed" position so as to maintain a retaining force on cam surface 142B.

A tool 200, as shown in Figure 3, may be inserted between the protrusion 122 and the end wall 136 to decouple the blade 106 from the collection chamber 104. The tool 200 includes one, and preferably two prongs coupled to a handle. The prongs are spaced a distance greater than the width of the stop mechanism 120, but narrower than the width of the protrusion 122. Alternatively, a pry bar may be inserted through an opening 124 (as shown in Figure 4) in an end 112' of a blade to extract the blade 106

from the collection chamber 104.

In an alternative embodiment, a blade may be inserted from the end opposite the end wall 136 and urged towards the end wall 136. The collection chamber may include a stop mechanism that contacts a portion of the cutting end of the blade.

Referring to FIGS. 6 and 7, there is illustrated an alternative embodiment of bone-harvesting instrument in accordance with the present invention. In this embodiment, two cantilevered springs 21 provide opposing forces that cause retention cams 9 to bear on pin follower 10 forcing blade tabs 13 forward against forward travel stops 19 and thereby securely retain blade 2 in its forward most position (loaded). In this position, blade 2 is also constrained laterally by side guides 22 and vertically by the blade tabs 13 being under the hold-down tabs 14.

Referring in particular to Figure 7, blade loading is achieved by holding the blade 2 between a finger and thumb at the spring 21 end of blade 2. Then it is placed between the side guides 22 while being angled and pulled backward causing blade catches 16 to contact back travel stops 15. In this position, insertion opening 7 is aligned with pin follower 10 and blade 2 can be lowered. Next, blade ends 23 are pushed forward with a finger or thumb causing forces to be applied to insertion cams 8 contacting pin follower 10. As more force is applied, the springs bend outwardly allowing blade 2 to move forward and eventually snap into loaded position as retention cams 9 bear on pin follower 10.

Blade removal is achieved using a prying instrument. Prying instrument 3 bears against handle pry surface 11 while it is pushed backward causing force to be applied to blade pry surface 24.

In the embodiment shown in Figures 6 and 7, instruments may be customized at the factory by bending reduced section 25 about the X-axis and/or Y-axis. A secure rotational grip, multiple facets, enables the surgeon to control the third degree of rotational freedom by simply gripping the handle at the desired Z-axis angle.

In use cutting edge 114 (Figure 2) or cutting edge 17 (Figure 6) is placed in contact with the donor bone surface and pulled backward causing graft material to be cut and flow through aperture 116 (Figure 2 ) or aperture 18 (Figure 6) into collection chamber 104 (Figure 2) or 20 (Figure 6).

Harvesting progress may be monitored by looking at view slot 118 (Figure 2) or in the case of the Figure 6 embodiment, distal view slot 4, side view slots and/or proximal view slot 6 and observing graft material in or close to the slot. These slots 5 are sufficiently narrow so as to prevent material from falling through them. Preferably slots 5 are in the range of 0.5 – 2 mm which is sufficient to permit the user to visually observe the graft material as it is collected, preventing material from falling through the slots. In order to better ensure material will not be lost by falling through the slots, the head of the instrument may be dipped into water or saline solution prior to use. Wetting the instrument causes the shavings to adhere to surfaces in the collection chamber.

After the material is harvested, the blade may be removed, and interior volume of the collection chamber may be used as a mixing area. The mixing area may be used to mix shavings of scraped bone and blood with other materials such as xenogeneic bone, allogenic bone, alloplastic material (hydroxyapatite), platelet rich plasma, and/or recombinant growth factors (BMP) to make a composition that can be later applied to an area of a patient needing a bone graft. A curette, or other standard instrument, may be used to move the graft material from the collection chamber to a desired recipient site.

Figures 8-16 illustrate yet another and preferred embodiment of the bone-harvesting instrument of the present invention.

The blade 202 in the embodiment of Figures 8-16 is similar to the blade 2 in the embodiment of Figure 7. The blade has a pair of cantilevered springs 221 which define an engagement hole 222, insertion cam 224, retention cam 226 and pin hole 228 formed adjacent the approximal end of the blade. One of the blade tab ends 230 includes a notch 232 or other indicia to differentiate it from the other blade tab end 234 to ensure cutting edge up orientation when the blade is mounted on the handle.

To load the blade, the blade is picked-up adjacent its tab ends 230, 234 using, for example, a hemostat 300 (or needle holder) and the blade is positioned on the tool, e.g., as shown in Figure 10.

Referring to Figure 11, the hemostat 300 is re-positioned, and used to apply force against the back of the blade tab ends 230, 234 using the pin 216 for leverage.

The force causes the springs 221 to bend outwardly allowing blade 202 to move forward and eventually snap into loaded position as retention cams 226 bear on pin follower 210.

Referring to Figures 12 and 13, blade removal is achieved by inserting the nose 302 of one jaw of the hemostat 300 into an aperture 240 formed in the midpoint of the blade 202. The nose 304 of the other jaw of the hemostat is applied to bear on the pin follower 210 and the hemostat is then used to apply force to the blade to back the blade out to where the pin follower is in the engagement hole 222. Referring to Figure 14, the hemostat is then repositioned, and used to lift and remove the blade from the handle.

The pin follower 210 and engagement hole 222 are sized so that spring force of the cantilevered springs 221 securely hold the blade preventing it from falling off so that the blade is held in place while the hemostat is switched from holding to applying force and vice versa.

Figure 15 illustrates how the blade 202 is packaged in a transparent plastic bag 401 and grasped with a hemostat 300 for the first time at the beginning of a grafting procedure. Figure 16 shows the hemostat 300 with lock 402 grasping the blade 202 and resting flat on a table surface 403 thereby providing safe temporary storage of the blade while the handle is being used to deliver graft material. If additional graft material is needed, the surgeon picks up the hemostat with the blade already grasped and loads it onto the handle.

The embodiment of Figures 8-16 has several features and advantages to prevent the blade from becoming loose. For one, if the blade is inadvertently pushed backward within the range of the retention cams, the blade will be restored to its harvested position upon removal of the pushing force. The retention cams have angles sufficiently steep to create a retention force that will overcome friction and restore the blade's position. Secondly, if the blade is inadvertently pushed backward beyond the range of the retention cams, the blade can not be moved further out of position. This is because the insertion cams have angles sufficiently shallow to cause friction to retain the blade's position and not allow the spring forces to move the blade further along. Moreover, even if the blade were inadvertently forced all the back to

the load position, the blade still would be prevented from falling off the handle because the follower pin 216 and engagement hole 222 are sized to cause spring force from the cantilever to spring blades 221 to provide spring force in the load position (blade position shown in figure 14).

The bone-harvesting instrument of the present invention has many advantages. These include:

(1) Low cost. Only three parts are used to provide all functions:

(a) cutting edge;

(b) aperture;

(c) collection chamber;

(d) view slots;

(e) graft delivery nose;

(f) customized head angles; and

(g) secure retention mechanism: guides, springs, cams, follower, stops, tabs, pry surfaces, etc.

(2) Highly secure blade retention. The angle on the face of insertion cams 8 is made shallow compared with the angle of the face on the retention cams 9. This provides relatively easy insertion and very positive retention. The prying feature allows the surgeon to easily overcome the high retention force. Additionally, handle pry surface 11 is sloped to accommodate a range of standard instrument sizes that can be used as the pry instrument 3 (see Figure 6). Thinner instruments may be positioned further down on the slope.

(3) Durable retention mechanism. Dual cantilevered springs apply opposing forces to the pin follower. Thus, very little force is applied to the handle material and handle wear is minimized. The pin follower can easily be made of a material that is harder than the blade (typically Rockwell 60C v. 55C) causing the blade to be the primary wearing part. Wear on the blades cams is not significant because blades may be replaced after a few uses (typically 1 to 4) to obtain new edges.

(4) Save and rapid blade handling. The design and the blade handling method enable the surgeon to initially grasp the blade with ease and then rapidly load and unload it from the handle without ever having to touch the small, sharp blade with his

fingers. Further, the method provides a convenient means to temporarily store the blade while the handle is being used to deliver graft material. Thus, the surgeon can rapidly and easily graft volumes of bone that are many times (2 – 8 or more) the volume of the collection chamber by rapidly changing from harvest mode (blade loaded) to deliver mode (blade unloaded) and vice versa.

(5) View slots. Slots in the blade permit viewing "through the metal" and thereby allow the blade and the handle to be made of opaque materials that are autoclaveable and reuseable.

(6) Angled head. Instruments can be readily customized at the users site by means of a flexible joint, e.g. ball and socket, or at the factory by bending reduced section 25 about the X-axis and/or the Y-axis. During surgery, the surgeon selects a handle with appropriate angles to facilitate access to the particular surgical site. Making all the handles the same, except for bends, enables the use of a common handle blank and a common blade. Economies of scale result from producing more of the same parts. Inventory costs also are reduced.

It should be understood that, while the present invention has been described in detail herein, the invention can be embodied otherwise without departing from the principles thereof, and such other embodiments are meant to come within the scope of the present invention as defined in the following claims.